

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Impact of removing prescription charges on health outcomes: protocol for a randomised controlled trial
<b>AUTHORS</b>	Cousins, Kimberly; Norris, Pauline; Horsburgh, Simon; Smith, Alesha; Keown, Shirley; Samaranayaka, Ariyapala; Marra, Carlo; Churchward, Marianna

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Green, Larry A. University of Colorado Denver School of Medicine, Family Medicine
<b>REVIEW RETURNED</b>	28-Feb-2021

<b>GENERAL COMMENTS</b>	Delightful to see a protocol that is designed to test a viable, implementable policy, using mixed methods, preceded by testing with pharmacies. What risk is associated with missing outcome variables because of care outside the public system providing necessary data is not clear. The dates shown in the protocol imply that the study has been concluded, but given plausible impact of the pandemic, the trial might be in progress. Whether or not this matters to accepting this for publication as a planned or ongoing study --I leave to the editors.
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<b>REVIEWER</b>	Bhandari, Deepak Civil Service Hospital, Department of Anesthesia and Critical Care
<b>REVIEW RETURNED</b>	10-Mar-2021

<b>GENERAL COMMENTS</b>	<p>Its look like a good study protocol however I have few queries.</p> <p>Your research question dictates "effect of removing prescription charges on health outcome" does this study plan to see the effect on all kind of patients meaning people with all kinds of disease ? How do you plan to address population with other chronic diseases who require much higher amount of prescribed drugs such as " chronic kidney disease" , " hypertension", "COPD" etc ? Will patients with other co morbid condition along with type two diabetes or mental health issues be excluded or included in the criteria?</p>
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### VERSION 1 – AUTHOR RESPONSE

**Reviewer 1 Comments:**

**1. What risk is associated with missing outcome variables because of care outside the public system providing necessary data is not clear.**

In New Zealand, acute care is only provided within the public system. It is therefore unlikely that there would be substantial missing outcome data arising from patients seeking care outside the public system.

The following phrase has been added to the paper on page 12 to clarify this and a relevant citation has been added: We will include all publicly-funded hospital and emergency department data (*in New Zealand, all acute care is provided within the public system*<sup>18</sup>). [Inserted text is in italics.]

**2. The dates shown in the protocol imply that the study has been concluded, but given plausible impact of the pandemic, the trial might be in progress. Whether or not this matters to accepting this for publication as a planned or ongoing study --I leave to the editors.**

At the time that this paper was submitted to the journal, data collection was not yet complete.

**Reviewer 2 Comments:**

**1. Your research question dictates "effect of removing prescription charges on health outcome" does this study plan to see the effect on all kind of patients meaning people with all kinds of disease?**

We do not intend to see the effect on all types of people with all kinds of diseases. The study evaluates the effect of removing prescription charges on health outcomes for participants who meet our inclusion criteria, as stated on Pages 9-10.

As such, we have provided additional detail about the research question in the abstract on Page 2, by specifying that the trial "will evaluate the effect of removing prescription charges on health outcomes and health care utilisation patterns *of people with low income and high health needs.*" [Inserted text is in italics.]

We have also clarified this in the final paragraph of the background section on Page 6: "The study will evaluate the effect of removing prescription charges on the usage of publicly-funded healthcare services *on people with low income and high health needs.*" [Inserted text is in italics.]

**2. How do you plan to address population with other chronic diseases who require much higher amount of prescribed drugs such as " chronic kidney disease", " hypertension", "COPD" etc ?**

This study aims to address only the population who meet our inclusion criteria, as stated on Pages 9-10 of the manuscript.

We appreciate that the study population doesn't represent everybody with chronic illness, but we needed to select populations that were clearly identifiable based on the available prescription data and that were likely to use multiple medications.

**3. Will patients with other co morbid condition along with type two diabetes or mental health issues be excluded or included in the criteria?**

Patients with other comorbidities are not excluded from the study. In fact, we would expect many of the patients to have other comorbidities, as prevalence of comorbidities is high in patients with Type 2 diabetes and mental health problems. If the randomisation of participants to the intervention or

comparison groups worked as intended, the prevalence of other comorbidities should be acceptably similar between the two groups; therefore, the impact of these comorbidities on the outcomes should also be equivalent in both groups.

We have specified in the text on page 10 that participants with other co-morbidities were not excluded from the study by adding the following sentence about exclusion criteria: *Participants will not be excluded if they have other health conditions in addition to those needed to meet the study inclusion criteria.*

**Additional editor's comments from 16 June 2021:**

- **Upon checking, we have noticed a citation of unpublished data on reference number 15. Please be informed that we do not allow citation of unpublished data in the reference list. With this, please ensure to remove the unpublished data in the reference and cite it instead within the main text of the main document with the name of the author who wrote the study and its title.**

The reference to an unpublished student report (formerly reference number 15) has now been removed, along with the accompanying phrase in the text.

The reference numbering has been adjusted to account for the removal of this reference and a Word comment has been added to the marked-up manuscript to explain this.

- **Please provide a more detailed contributorship statement in the main document. It needs to mention all the names/initials of authors along with their specific contribution/participation for the article. This should be stating how each author contributed to the article. It should discuss on the planning, conduct and reporting of the work in your paper. You may also consider the conception and design, acquisition of data or analysis and interpretation of data, etc. The statement in the ScholarOne system and main document should matched.**

The following contributorship statement has been included and replaces the previous statement in the Author contribution section of the paper and the ScholarOne system:

*PN is the principal investigator and conceived of the study. A feasibility study was carried out by PN, KC, SK, ASmith, and SH. PN and KC designed the study and drafted the study protocol, with input from ASmith, ASamaranayaka, CM, SK, SH, MC. ASamaranayaka is the biostatistician on the study and assisted with overall design and sample size calculations. CM provided detail for the health economic aspects of the study. SH and ASmith provided detail for the health outcomes data. MC and SK provided study site-specific advice on participant recruitment and Māori and Pacific input into the study. All authors read and approved the final manuscript. All authors meet the four ICMJE criteria for authorship. [Inserted text in italics.]*

- **Please provide a point-by-point response to the Editor's comments and reviewer's comments.**

This document is the point-by-point response to the Editor's and reviewers' comments.

**VERSION 2 – REVIEW**

<b>REVIEWER</b>	Bhandari, Deepak Civil Service Hospital, Department of Anesthesia and Critical Care
<b>REVIEW RETURNED</b>	05-Jul-2021

<b>GENERAL COMMENTS</b>	Well structured study protocol. Hope the study will provide a better insight to barrier created by prescription charge on accessibility of healthcare system.
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